IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 4:09-CV-11340 (FDS)
CENTOCOR ORTHO BIOTECH, INC. and CENTOCOR BIOLOGICS, LLC,	)	
Defendants.	)	

CENTOCOR'S MOTION FOR RECONSIDERATION OF TWO ASPECTS OF THE MARCH 9, 2012 ORDER ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

I. INTRODUCTION 1

II. STANDARD FOR RECONSIDERATION 1

III. CENTOCOR REQUESTS RECONSIDERATION OF THE COURT'S DENIAL OF SUMMARY JUDGMENT THAT CERTAIN CLAIMS OF THE 485 PATENT ARE INVALID FOR LACK OF WRITTEN DESCRIPTION 2

A. Brief Summary Of Centocor's Reconsideration Argument On Written Description 2

B. The Error Here Is An Issue Of Law That Is Appropriately Corrected Through Reconsideration 3

C. Procedural Background To The Present Motion 4

D. The Patent Must Evidence Possession Of The Claimed Subject Matter For The Written Description Requirement To Be Met 5

E. The Order Denying Summary Judgment Of Claims 15, 18, 25 And 26 Was Based On An Erroneous Construction Of Those Claims As Limited To Antibodies That Bind A p40 Subunit 5

1. Claims 15, 18, 25 and 26 are not limited to antibodies that bind a p40 subunit 6

2. The error of construction was significant to the Court's ruling 7

F. The Order Denying Summary Judgment Of Claims 1, 11, 15, 19, 24, 25 And 26 Was Based On An Erroneous Construction Of Those Claims As Limited To Antibodies That Bind To IL-12 And/Or IL-23 8

1. Claims 1 and 15 are not limited to antibodies that bind to IL-12 or IL-23 8

2. Claims 11, 19, 24, 25 and 26 are not limited to antibodies that bind to IL-12 or IL-23 9

3. The error of construction was significant to the Court's ruling 10

IV. CENTOCOR REQUESTS RECONSIDERATION OF THE COURT'S DENIAL OF SUMMARY JUDGMENT THAT THE COMPOSITION CLAIMS ARE INVALID AS ANTICIPATED BY CENTOCOR'S PRIOR INVENTION 11

V. CONCLUSION 16

TABLE OF AUTHORITIES

Page(s)

CASES

Ariad Pharms., Inc. v. Eli Lilly & Co.,
598 F.3d 1336 (Fed. Cir. 2010).....4, 5

Automated Business Cos. v. ENC Tech. Corp.,
No. H-06-1032, 2009 WL 3674507 (S.D. Tex. Oct. 30, 2009).....3

Billups-Rothenberg, Inc. v. Associated Reg'l and Univ. Pathologists, Inc.,
642 F.3d 1031 (Fed. Cir. 2011).....4

Cognex Corp. v. Electro Scientific Indus., Inc.,
242 F. Supp. 2d 47 (D. Mass. 2003).....3

Falana v. Kent State Univ.,
669 F.3d 1349 (Fed. Cir. 2012).....12

Hess v. Adv. Cardiovascular Sys., Inc.,
106 F.3d 976 (Fed. Cir. 1997).....15

In re Stempel,
241 F.2d 755 (C.C.P.A. 1957).....14

In re Zletz,
893 F.2d 319 (Fed. Cir. 1989).....14

Itex, Inc. v. Mount Vernon Mills, Inc.,
No. 08-C-1224, 2011 WL 2470343 (N.D. Ill. Jun. 20, 2011).....3

Jamesbury Corp. v. United States,
518 F.2d 1384 (Ct. Cl. 1975).....15

Kimberly-Clark Corp. v. Procter & Gamble Distributing Co.,
973 F.2d 911 (Fed. Cir. 1992).....13

Markman v. Westview Instruments, Inc.,
517 U.S. 370 (1996).....3

Perkins v. Engs,
118 F.2d 924 (C.C.P.A. 1941).....13

Pfaff v. Wells Electronics, Inc.,
525 U.S. 55 (1998).....14

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005).....7

Ruiz Rivera v. Pfizer Pharms., LLC,
521 F.3d 76 (1st Cir. 2008).....1

Samson v. Crittenden,
1989 Pat. App. LEXIS 25 (B.P.A.I. Sept. 27, 1989).....13

Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.,
440 F. Supp. 2d 120 (D. Conn. 2006).....3

Vanderbilt Univ. v. ICOS Corp.,
601 F.3d 1297 (Fed. Cir. 2010).....13, 14

Vas-Cath Inc. v. Mahurkar,
935 F.2d 1555 (Fed. Cir. 1991).....5

STATUTES

35 U.S.C. § 101.....13, 15

35 U.S.C. § 102.....13

35 U.S.C. § 111.....15

35 U.S.C. § 112.....14

35 U.S.C. § 256.....16

OTHER AUTHORITIES

U.S. Const. art. I, § 8, cl. 8.....15

I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 59(e), Centocor Ortho Biotech, Inc. and Centocor Biologics, LLC ("Centocor") respectfully move for reconsideration of two aspects of the March 12, 2012 Order on Cross-Motions for Summary Judgment (D.I. 333) ("Order"):

First, Centocor requests reconsideration of the Court's denial of summary judgment that Claims 1, 11, 15, 18, 19, 24, 25, and 26 of U.S. Patent No. 7,504,485 ("the 485 patent") are invalid for lack of written description (D.I. 196, Centocor Motion No. 3), because the Order reflects a manifest error of law with regard to the scope of those claims.

Second, Centocor requests reconsideration of the Court's denial of summary judgment that the "composition claims" are invalid as anticipated under 35 U.S.C. § 102(g)(2) by Centocor's prior invention (D.I. 205, Centocor Motion No. 6), because the Order reflects a manifest error of law with regard to the question of whether Abbott can prove an invention date for its composition claims prior to the time of the joint conception of those claims.

II. STANDARD FOR RECONSIDERATION

The Court has "substantial discretion and broad authority" to grant a motion for reconsideration pursuant to Federal Rule of Civil Procedure 59(e). *Ruiz Rivera v. Pfizer Pharms., LLC*, 521 F.3d 76, 81-82 (1st Cir. 2008). Granting a motion for reconsideration is appropriate "where the movant shows a manifest error of law," "newly discovered evidence," or that the court "has patently misunderstood a party . . . or has made an error not of reasoning but apprehension." *Id.* (affirming the district court's grant of a motion for reconsideration and grant of summary judgment based on legal insufficiency of evidence).

III. CENTOCOR REQUESTS RECONSIDERATION OF THE COURT'S DENIAL OF SUMMARY JUDGMENT THAT CERTAIN CLAIMS OF THE 485 PATENT ARE INVALID FOR LACK OF WRITTEN DESCRIPTION

A. Brief Summary Of Centocor's Reconsideration Argument On Written Description

Centocor requests reconsideration of the Court's denial of summary judgment that Claims 1, 11, 15, 18, 19, 24, 25, and 26 of the 485 patent are invalid for lack of written description (D.I. 196, Centocor Motion No. 3), because the Order reflects that the decision was premised on a manifest error of law with regard to the scope of these claims. More specifically, the Court appears to have mistakenly considered the written description of these claims as if the claims were limited to antibodies that bind to IL-12, IL-23, or the p40 subunit that these interleukins have in common. That is not an accurate claim construction.

Some of these claims – for example, Claims 15, 18, 25, and 26 – encompass antibodies capable of binding to any area of a target antigen. They are not limited to antibodies that bind to a p40 subunit. These claims would be broad enough to encompass antibodies that bind to the p19 subunit of p19/p40 (IL-23), even though the patent is silent with respect to whether the inventors' antibodies could bind anything other than a p40 subunit. Nothing in the patent evidences that the inventors were in possession of this broad group of antibodies, and there can be no dispute that there is no written description support for claims to such antibodies.

Others of the claims – for example, Claims 1, 11, 15, 19, 24, 25, and 26 – are not limited to antibodies that bind to the target antigen IL-12 or p19/p40 (IL-23). Claims 1 and 11, for example, only limit the antibody to one that is "capable" of binding to the p40 subunit of an antigen. They do not limit the target antigen to IL-12 or IL-23 and, therefore, encompass antibodies capable of binding to interleukins that have still not been identified, but happen to share a common p40 subunit with IL-12. Claims 15, 19, 24, 25, and 26 also fail to limit the

target antigen to IL-12 or IL-23 and, as discussed above, do not even require that the claimed antibodies be capable of binding to a p40 subunit. Nothing in the patent evidences that the inventors were in possession of this broad group of antibodies, and there can be no dispute that there is no written description support for claims to such antibodies.

The Court appears to have mistakenly considered the written description of these claims as if the claims were limited to antibodies that bind to IL-12, IL-23, or the p40 subunit that these interleukins have in common. That is an error of law that can be rectified through reconsideration.

B. The Error Here Is An Issue Of Law That Is Appropriately Corrected Through Reconsideration

Claim construction is an issue of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). Therefore, a mistaken understanding of the scope of the patent claims is an error of law. *See Cognex Corp. v. Electro Scientific Indus., Inc*., 242 F. Supp. 2d 47, 48-49 (D. Mass. 2003) (granting motion for reconsideration to modify the district court's claim construction order); *see also Automated Business Cos. v. ENC Tech. Corp*., No. H-06-1032, 2009 WL 3674507, at *15 (S.D. Tex. Oct. 30, 2009) (Ex. 98) (granting motion for reconsideration because the "claim construction rulings constituted manifest errors of law"); *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc*., 440 F. Supp. 2d 120, 124 (D. Conn. 2006) (granting motion for reconsideration based on an error in claim construction); *Itex, Inc. v. Mount Vernon Mills, Inc.*, No. 08-C-1224, 2011 WL 2470343, at *6 (N.D. Ill. Jun. 20, 2011) (Ex. 99) (same).

Because the Order denying summary judgment that Claims 1, 11, 15, 18, 19, 24, 25, and 26 are invalid for failing to meet the written description requirement was denied on the basis of an error of law with respect to the scope of these claims, Centocor requests reconsideration of the ruling.

C. Procedural Background To The Present Motion

Centocor's original motion was directed to a broader group of claims than are the subject of the present motion. Originally, Centocor moved for summary judgment that claims in the 485 Patent that were not limited to IL-12 as a target antigen – i.e., including claims to antibodies targeting a p19/p40 molecule – were invalid under the written description requirement, because the p19/p40 molecule was not adequately described. The Court denied this motion, finding a factual dispute "regarding both the state of the art at the effective filing date and the sufficiency of the disclosed antibodies in representing the claimed genuses" (Order at 49). The Order focused on the statement in the patent regarding the expectation that p40-binding antibodies would bind to p19/p40, on the purported disclosure in the patent of antibody species that bind to the p40 subunit of IL-12, and on literature purportedly describing IL-23, the name later given to p19/p40 (Order at 46-49).

Centocor is *not* requesting reconsideration for those claims that are limited to antibodies that bind to IL-23 (a p19/p40 molecule) or that bind to the p40 subunit that IL-12 and IL-23 have in common. For these claims, Centocor is deferring the issue for trial based on the Court's finding that there is a dispute of fact.[1] The present motion is directed to those claims that are not

[1] Although not a basis for this request for reconsideration, Centocor does wish to note for the Court (because this issue may come up at trial) that the Order refers to a November 2000 article listed on the first page of the 485 Patent and appears to credit a November 2000 article listed on the first page of the 485 Patent as part of the written description for the patent claims (Order at 44 and 48). However, the citation of the Oppman article, on the first page of the patent under "References Cited," is not part of the disclosure that may be considered for determining whether there is adequate written description for the claims. The Patent Office adds a list of "References Cited" when it prints the patent. These include references cited by the patent applicant or the examiner during prosecution. The November 2000 article was not part of the original patent disclosure; nor could it have been, as the patent application was filed months earlier, in March 2000. Since the November 2000 article post-dated the filing date of the patent, it is legally irrelevant to the question of written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010); *Billups-Rothenberg, Inc. v. Associated Reg'l and Univ. Pathologists, Inc.*, 642 F.3d 1031, 1037 (Fed. Cir. 2011) (written description requirement cannot be satisfied through references to later-acquired knowledge).

limited to antibodies that bind to IL-12, IL-23, or the p40 subunit, because there can be no dispute that there is no written description support for claims of this broader scope.

D. The Patent Must Evidence Possession Of The Claimed Subject Matter For The Written Description Requirement To Be Met

The test for sufficient written description is whether the disclosure in the patent reasonably conveys to those skilled in the art that the inventor had possession of the *claimed subject matter* as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (test is whether applicant was in possession of the invention, meaning "whatever is now claimed"). The written description requirement must allow persons of ordinary skill in the art to recognize that the inventor actually invented what is claimed. *Ariad*, 598 F.3d at 1351. When the claim covers a genus, one skilled in the art must be able to "visualize or recognize" the members of the genus. *Id.* at 1350.

E. The Order Denying Summary Judgment Of Claims 15, 18, 25, And 26 Was Based On An Erroneous Construction Of Those Claims As Limited To Antibodies That Bind A p40 Subunit

The Court considered that the 485 patent claims encompassed "antibodies that bind to the p40 subunit of both IL-12 and IL-23" (Order at 44). It appears to have been important to the Court's reasoning that the claimed antibodies bind to this p40 subunit because this "specific p40 subunit to which the disclosed antibodies bind" was a described feature that the IL-12 and IL-23 antigens have in common (Order at 46-47, 48) and because the patent disclosed that antibodies which bind to p40 alone, in the context of the IL-12 antigen, would be "expected" to also neutralize the p19/p40 antigen (Order at 44). Moreover, in finding a dispute of fact, the Court relied on evidence from the Rebuttal Expert Report of Abbott Expert Dr. Marks, where he

identified antibody species disclosed in the patent that allegedly bind to the p40 subunit of IL-12 (Order at 48, including footnote 40).[2]

1. Claims 15, 18, 25, and 26 are not limited to antibodies that bind a p40 subunit

Although the Court's construction of the scope of the 485 patent claims as encompassing only antibodies that bind to the p40 subunit is correct with respect to most of the claims in the patent, it is incorrect with respect to Claims 15, 18, 25, and 26. Each of these claims recites antibodies that bind to an antigen that *has* a p40 subunit, but none of these claims requires that the antibody *bind to* that p40 subunit, as opposed to some other area of the antigen. These claims are:

> 15. A pharmaceutical composition comprising an isolated human antibody, or antigen-binding portion thereof, which is capable of binding to an interleukin comprising a p40 subunit, and further comprising an additional agent.
>
> 18. The composition of claim 15, wherein the interleukin comprises a p40 subunit and a p19 subunit.
>
> 25. The composition of claim 15, wherein the antibody, or antigen binding portion thereof, neutralizes a biological activity of the interleukin.
>
> 26. The composition of claim 25, wherein the antibody, or antigen binding portion thereof, inhibits phytohemagglutinin blast proliferation in an in vitro PHA assay with an IC_{50} of 1 x 10^{-9} or less, or which inhibits human IFNγ production with an IC_{50} of 1 x 10^{-10} M or less.

(Ex. 2 at col. 382, l. 64- col. 383, l. 33).[3]

These claims do not require that the antibody bind *to* the p40 subunit. This is apparent not only from the plain language of the claims, which makes no reference to the area of binding, but also from the language of Claim 19. Claim 19 is dependent on Claim 15 and adds the

---

[2] Indeed, in its Opposition to Centocor's Motion No. 3, Abbott itself characterized Dr. Marks expert report statements as relating to species of antibodies that *bind to the p40 subunit* (D.I. 259 at p. 8).

[3] Exhibit Nos. 1-97 refer to exhibits submitted in support of Centocor's Motions for Summary Judgment. Exhibits 98-103 are submitted herewith.

limitation that the antibody "binds to an epitope of the p40 subunit." (Ex. 2 at col. 383, ll. 7-9). Under the doctrine of claim differentiation, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp*., 415 F.3d 1303, 1315 (Fed. Cir. 2005). Thus, the fact that dependent Claim 19 adds the requirement that the antibody bind to the p40 subunit gives rise to the presumption that independent Claim 15 is broader and does *not* require that the antibody bind to the p40 subunit. Claims 18, 25, and 26 are all dependent upon Claim 15 and also lack any requirement that the antibody bind to the p40 subunit.

Claims 15, 18, 25, and 26, therefore, are broad enough to encompass antibodies that bind to the p40 subunit *or anywhere else* on a target antigen. The antibodies recited in claim 18 could bind to the p19 subunit of IL-23, and for claims 15, 25, and 26, the antibodies could bind to some as-yet-undefined subunit of some as-yet-unidentified antigen. The Court's understanding that all of the claims subject to Centocor's summary judgment motion were "claims that encompass antibodies that bind to the p40 subunit" was in error.

2. The error of construction was significant to the Court's ruling

This is an error of significance to the Court's decision denying summary judgment of invalidity of these claims. Because Claims 15, 18, 25, and 26 are broad enough to encompass antibodies that bind not only to the p40 subunit of an antigen, but to any other area of the antigen, the 485 patent must adequately describe that the inventors were in possession of antibodies that bind to something other than the p40 subunit. It does not do so.

The only antibodies disclosed in the patent are antibodies that bind to a p40 subunit. In finding a dispute about the adequacy of written description, the Court relied on the patent's statement that antibodies which "recognize p40 *alone*" would be expected to neutralize p19/p40

(Order at 46-47, emphasis added). But that statement does not support the full scope of broader claims that are not limited to antibodies that recognize or bind to p40. There is no description in the patent that would allow a reasonable jury to conclude that the applicants invented or were in possession of antibodies that bind to any subunit of an antigen, as long as the antigen happens to include a p40 subunit. Disclosing antibodies that bind to a p40 subunit does not suggest that the disclosed antibodies would be "expected" to bind to any interleukin that includes this subunit. It also does not suggest that these antibodies would bind to a p19 subunit. The full scope of the claimed antibodies encompassed by Claims 15, 18, 25, and 26 cannot be visualized. Centocor respectfully requests reconsideration of the Court's Order denying summary judgment that Claims 15, 18, 25, and 26 are invalid for failure to meet the written description requirement.

F. The Order Denying Summary Judgment Of Claims 1, 11, 15, 19, 24, 25, And 26 Was Based On An Erroneous Construction Of Those Claims As Limited To Antibodies That Bind To IL-12 And/Or IL-23

The Order reflects an additional error with respect to the scope of certain of the claims in apparently relying on an understanding that the claims of the 485 patent encompass only antibodies that bind to the antigens IL-12 and/or IL-23. Although that is the case with a number of the claims, it is not the case with respect to Claims 1, 11, 15, 19, 24, 25, and 26.

1. Claims 1 and 15 are not limited to antibodies that bind to IL-12 or IL-23

Claims 1 and 15 are broad enough to encompass antibodies that bind to antigens other than IL-12 and IL-23. For reference, these claims recite as follows:

> 1. A pharmaceutical composition comprising an isolated human antibody, or antigen-binding portion thereof, which is capable of binding to an epitope of the p40 subunit of IL-12, and further comprising an additional agent.

(Ex. 2 at col. 381, ll. 33-36)

> 15. A pharmaceutical composition comprising an isolated human antibody, or antigen-binding portion thereof, which is capable of binding to an interleukin comprising a p40 subunit, and further comprising an additional agent.

(Ex. 2 at col. 382, ll. 64-67).

The literal language of these claims would encompass antibodies that bind to antigens other than IL-12 or IL-23, including as-yet-unidentified antigens that happen to have a p40 subunit in common with IL-12. The doctrine of claim differentiation confirms this claim scope.

Claims 2-4 depend from claim 1 and claims 17 and 18 depend from claim 15. These dependent claims more specifically identify the target antigen as IL-12 (or a p40/p35 molecule) or IL-23 (or a p40/p19 molecule) (Ex. 2 at col. 381, ll. 37-49, col. 383, ll. 3-6). Pursuant to the doctrine of claim differentiation, the fact that these limitations are added by dependent claims confirms that claims 1 and 15 more broadly encompasses antibodies that bind to other target antigens.

2. Claims 11, 19, 24, 25, and 26 are not limited to antibodies that bind to IL-12 or IL-23

Claims 11, 19, 24, 25, and 26 each depend from claims 1 or 15 and are also broad enough to encompass antibodies that bind to antigens other than IL-12 and IL-23. For reference, these claims recite as follows:

> 11. The composition of any one of claims 1-4, wherein the antibody, or antigen binding portion thereof, dissociates from the p40 subunit of IL-12 with a K_d of $1x10^{-10}$ M or less or a K_{off} rate constant of $1x10^{-3}$ s^{-1} or less, as determined by surface plasmon resonance.

> 19. The composition of any one of claims 15-18, wherein the antibody, or antigen binding portion thereof, binds to an epitope of the p40 subunit.

> 24. The composition of claim 15, wherein the antibody, or antigen binding portion thereof, dissociates from the p40 subunit of the interleukin with a K_d of $1x10^{-10}$ M or less or a k_{off} rate constant of $1x10^{-3}$ s^{-1} or less, as determined by surface plasmon resonance.

> 25. The composition of claim 15, wherein the antibody, or antigen binding portion thereof, neutralizes a biological activity of the interleukin.

> 26. The composition of claim 25, wherein the antibody, or antigen binding portion thereof, inhibits phytohemagglutinin blast proliferation in an in vitro assay with an IC_{50} of 1 x 10^{-9} M or less, or which inhibits human IFNγ production with an IC_{50} of 1 x 10^{-10} M or less.

(Ex. 2 at col. 382, l. 40 – col. 383, l. 33).

These dependent claims do not add any further limitations on the target antigen. As discussed above, the literal language of claims 1 and 15 would encompass antibodies that bind to antigens other than IL-12 or IL-23, including as-yet-unidentified antigens that happen to have a p40 subunit in common with IL-12. Since these dependent claims do nothing to further limit the target antigen, they, too, encompass antibodies that bind to antigens other than IL-12 or IL-23.

3. The error of construction was significant to the Court's ruling

None of Claims 1, 11, 15, 19, 24, 25, and 26 is limited to antibodies that bind to IL-12 or IL-23. Yet, the Order discusses all of the 485 patent claims as if they were so limited.[4] This is incorrect, and this mistake as to the scope of the claims is an error of law that was significant to the Court's decision denying summary judgment of invalidity of these claims. Because Claims 1, 11, 15, 19, 24, 25, and 26 are broad enough to encompass antibodies not only to IL-12 and IL-23, but to any undefined antigen that happens to have a p40 subunit, the description in the 485 patent must adequately describe that the inventors were in possession of antibodies not just to IL-12 and IL-23, but also of antibodies to all antigens that have a p40 subunit. It does not do so.

The only two target antigens mentioned in the patent are IL-12 and the p19/p40 entity (later called IL-23). With respect to the latter, the patent states that it is "expected" that the antibodies that bind to the p40 subunit of IL-12 will also bind to p19/p40 (Order at 44). The Court found that there is a genuine dispute of fact regarding whether the patent disclosure

[4] Centocor addressed the scope of these claims at the December 7, 2011, hearing. (See D.I. 325, Transcript of Motion Hearing Held on Dec. 7, 2011 Before Judge Dennis F. Saylor IV, at pp. 12-14, 23-24).

evidences that the inventors were in possession of antibodies to IL-23 (Order at 46-49); however, there is no disclosure in the patent of *other* target antigens. The patent does not attempt to identify such other antigens, to describe their structure, or to describe antibodies that do or could be expected to bind to them. Since there is no disclosure of these other antigens, there is no description in the patent, as there is for p19/p40, that the disclosed antibodies would be "expected" to bind to them. Nor is there record evidence of any possible prior art knowledge of other target antigens in March 2000.

The asserted claims in the 485 patent do not claim the antibodies by their structure, but rather by their ability to bind to an antigen. The patent cannot evidence that the inventors invented, or were in possession of, antibodies to antigens that are neither defined nor described – or may not even have yet been discovered. The full scope of the claimed antibodies encompassed by the claims cannot be visualized if the target to which they bind is not even known. There is no evidence from which a reasonable jury could conclude that, as of March 2000, the 485 patent applicants were in possession of the entire scope of Claims 1, 11, 15, 19, 24, 25, and 26.

Centocor respectfully request reconsideration of the Court's Order denying summary judgment that these claims are invalid for failure to meet the written description requirement.

IV. CENTOCOR REQUESTS RECONSIDERATION OF THE COURT'S DENIAL OF SUMMARY JUDGMENT THAT THE COMPOSITION CLAIMS ARE INVALID AS ANTICIPATED BY CENTOCOR'S PRIOR INVENTION

Centocor respectfully requests reconsideration of the Order denying Centocor's motion for summary judgment that the composition claims, claims 64 and 70 of the 128 patent and claims 1-4, 6-11, 15-19, and 24-26 of the 485 patent, are invalid under 35 USC § 102(g)(2) as anticipated by Centocor's prior invention of a composition that included the Stelara ustekinumab antibody (part of Centocor Motion No. 6). The Order is based on a manifest error of law, namely,

that Abbott can prove a date of invention for the composition claims ***prior to*** the August 1998 date on which joint inventor, Stuart Friedrich, started his collaboration with the other inventors.

Centocor has proven an April 30, 1998 invention date for its Stelara antibody (Order at 61) – an antibody Abbott contends to be covered by each of the composition claims. Abbott needs to prove that "the invention" of its composition claims was made before April 30, 1998, in order to avoid having these claims anticipated by the Stelara invention. For each of the Abbott patent claims at issue, Dr. Stuart Friedrich was named as one of the joint inventors. Because Dr. Friedrich's collaboration with the other inventors did not begin until at least *August* 1998, Centocor contends that, as a matter of law, Abbott cannot prove a pre-*April* 1998 invention date.

As explained below, the Court appears to have mistakenly understood that Abbott could prove an earlier invention date by proving that some group invented a species that fell within these claims before Dr. Friedrich started collaborating on the project (Order at 62). That is an error of law. Although prior invention of a genus can be shown by prior invention of a single species, that can only be done when the species invention was *made by all of the inventors of the claim*. There can be no invention until there is a conception of the invention. Every inventor must contribute to the conception or they are not an inventor. Here, it is undisputed that Dr. Friedrich is one of the inventors of the composition claims, so, as a matter of law, there cannot have been an invention date for these claims at least until he started participating in the collaboration and could have contributed to the conception.

As recognized in the Court's summary judgment Order, "a person must contribute to the conception of the claimed invention to qualify as a joint inventor" (Order at 62). "Thus, the critical question for joint conception is who conceived, as that term is used in the patent law, the subject matter of the claims at issue." *Falana v. Kent State Univ.*, 669 F.3d 1349, slip op. at 12

(Fed. Cir. 2012) (Ex. 100). "The interplay between conception and collaboration *requires that each co-inventor engage with the other co-inventors to contribute to a joint conception*." *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1303 (Fed. Cir. 2010) (emphasis added). Thus, prior to the time of "engagement" (or collaboration) between the joint inventors, there can be no "joint conception" – and there can, therefore, be no invention date prior to the time of collaboration between the joint inventors.[5] *See Samson v. Crittenden*, 1989 Pat. App. LEXIS 25, at *11 (B.P.A.I. Sept. 27, 1989) (Ex. 101) ("Since [the last inventor] did not become involved with the project until late November 1984, only activities which occurred after that time may be relied upon by [the joint inventive group] to establish joint conception and reduction to practice on their behalf."); *Perkins v. Engs*, 118 F.2d 924, 928 (C.C.P.A. 1941) (It was not error for Board of Patent Appeals to refuse to consider any testimony of appellants prior to their collaboration since "[t]he question of priority must be determined from the beginning of the joint activities of appellants.").

That Abbott cannot prove a prior invention by showing that only some of the inventors invented a species before Centocor's invention date is apparent from the plain language of Section 102(g)(2) which provides that "a *person* shall be entitled to a patent unless . . . before *such person's* invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2) (emphasis added). In other words, the relevant date for purposes of 102(g)(2) is the date on which the "person" entitled to the patent – the *inventors*, pursuant to 35 U.S.C. § 101 – made the *invention*. The

[5] The requirement for collaboration among the joint inventors exists even though, under 35 U.S.C. § 116, (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent. *Kimberly-Clark Corp. v. Procter & Gamble Distributing Co.*, 973 F.2d 911, 916-17 (Fed. Cir. 1992) (some quantum of collaboration or connection is required in order for persons to be "joint" inventors under 35 U.S.C. § 116).

word "invention" in the Patent Act refers to the inventors' *conception*, *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 60 (1998), and there cannot be a conception of a joint invention until all of the joint inventors have collaborated. *See Vanderbilt Univ.*, 601 F.3d at 1303. Here, that means that there cannot have been an invention of the composition claims prior to Dr. Friedrich's participation in the collaboration.

The cases relied upon in the Order do not hold otherwise. In *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989) and *In re Stempel*, 241 F.2d 755, 759-60 (C.C.P.A. 1957), there is no suggestion that the invention date relied upon by the patent applicant to predate prior art was an invention made by only a subset of named joint inventors. In fact, in each of the cases, there was only a single inventor/patent applicant.

Centocor does not disagree with the Court's statement that "it is plausible that Abbott invented a species of pharmaceutical composition within the scope of its claims before Centocor's priority date of April 30, 1998, but nevertheless required contributions from Mr. Friedrich after that date in order to establish the patentability of Abbott's genus claims under 35 U.S.C. § 112." (Order at 62). Any species or compositions developed by Abbott prior to Centocor's April 1998 invention date may reflect the invention of certain other genus claims in the 128 and 485 patents where Mr. Friedrich is *not* an inventor (*see, e.g.*, claims 1-15, 27-40, 50-63 of '128 patent; Ex. 35 at 9). But as soon as the Mr. Friedrich made an inventive contribution to expand and/or modify any of these earlier inventions – including by providing inventive contributions necessary for the composition claims to allegedly meet the requirements of 35 U.S.C. § 112 – a *new invention* was made and that new invention has a new conception date. That conception date can be no earlier than the time that Mr. Friedrich became involved.

Naming the true inventors on a patent is not an administrative formality. Quite the contrary, it is required for a valid patent. The Constitution grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to . . . *Inventors* the exclusive Right to their . . . Discoveries." U.S. Const. art. I, § 8, cl. 8 (emphasis added). The Patent Statute provides that "*[w]hoever invents* . . . any new and useful . . . composition of matter … may obtain a patent therefor." 35 U.S.C. § 101. Failure to name the proper inventor(s) renders a patent invalid. *Jamesbury Corp. v. United States*, 518 F.2d 1384, 1395 (Ct. Cl. 1975) ("[T]he inclusion of more or less than the true inventors in a patent renders it void . . . .").

An application for patent must be made by the inventor. 35 U.S.C. § 111. Here, Abbott named Dr. Friedrich as an inventor on the 128 and 485 Patents. Dr. Friedrich executed a Declaration stating that he is a true and correct inventor on each of the patents (Ex. 102 at COBI01288637; Ex. 103 at COBI01290006). In response to Centocor's interrogatory about inventorship with respect to particular claims, Abbott stated that Dr. Friedrich is one of the joint inventors of each of the composition claims (Ex. 35 at 9). Abbott maintained that position in response to Centocor's summary judgment motion. In short, there is no dispute that Dr. Friedrich is an inventor on each of the composition claims. There is also no dispute that Dr. Friedrich did not begin work on the claimed inventions before August 1998. Accordingly, as a matter of law, there cannot have been an invention date for these claims before he started participating in the collaboration.

The Order suggests that Dr. Friedrich may have been misjoined as an inventor on the patents, but Abbott has not alleged misjoinder. To the contrary, it has consistently represented that Dr. Friedrich is a properly named inventor. And it is presumed that the named inventors on a patent are correct. *Hess v. Adv. Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997).

Even if Dr. Friedrich was misjoined as an inventor, that error can only be corrected if the error was made through no deceptive intention of Dr. Friedrich. 35 U.S.C. § 256. Where Dr. Friedrich must be presumed to be a correctly named inventor, and Abbott has steadfastly maintained that he is indeed an inventor of the composition claims, Abbott should not avoid summary judgment based on a hypothetical, contrary supposition.

Centocor respectfully submits that the Court's denial of its motion for summary judgment motion that the composition claims are invalid under 35 USC § 102(g)(2) was in error, based on an error of law. Contrary to the Court's statement on page 62 of the Order, Abbott ***cannot*** prove an "invention date" of the composition claims earlier than the date Mr. Friedrich joined and contributed to the conception of those claims. Centocor respectfully requests, following reconsideration of this issue, that the Court grant Centocor's motion.

V. CONCLUSION

Centocor respectfully asks that the Court reconsider two aspects of its March 12, 2012 Order on Cross-Motions for Summary Judgment, as discussed above. Upon reconsideration, Centocor requests that the Court grant (1) summary judgment that Claims 1, 11, 15, 18, 19, 24, 25, and 26 of the 485 patent are invalid for lack of written description, and (2) summary judgment that the composition claims are invalid as anticipated under 35 U.S.C. § 102(g)(2).

Dated: March 23, 2012

By: Dianne Elderkin

Dianne B. Elderkin (pro hac vice)
delderkin@akingump.com
Barbara L. Mullin (pro hac vice)
bmullin@akingump.com
Steven D. Maslowski (pro hac vice)
smaslowski@akingump.com
Angela Verrecchio (pro hac vice)
averrecchio@akingump.com
Matthew A. Pearson (pro hac vice)

mpearson@akingump.com
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
215-965-1200
FAX: 215-965-1210

Emily C. Johnson (pro hac vice)
johnsone@akingump.com
AKIN GUMP STRAUSS HAUER & FELD LLP
Robert S. Strauss Building
1333 New Hampshire Avenue N.W.
Washington, DC 20036
202-887-4000
FAX: 202-887-4288

Heather B. Repicky (BBO # 663347)
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
617-439-2000
FAX: 617-310-9000

Attorneys For Defendants
CENTOCOR ORTHO BIOTECH, INC. and
CENTOCOR BIOLOGICS, LLC

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing **CENTOCOR'S MOTION FOR RECONSIDERATION OF TWO ASPECTS OF THE MARCH 9, 2012 ORDER ON CROSS-MOTIONS FOR SUMMARY JUDGMENT** was electronically mailed to counsel of record on March 23, 2012 through the Court's ECF notification system.

_/Angela Verrecchio/_____
Angela Verrecchio